REMARKS

As an initial matter, the Office Action included a restriction requirement for the pending claims between Group I (claims 1-43) and Group II (claims 44-63). The claims of Group I were provisionally elected. Applicant hereby confirms this provisional election.

Currently, claims 64-88, including independent claim 64, are pending in the present application. Independent claim 64, for example, is directed to a method for detecting an analyte within a test sample. The method comprises providing a lateral flow assay device that comprises a porous membrane in fluid communication with phosphorescent particles conjugated with a specific binding member. The phosphorescent particles comprise a phosphorescent label encapsulated within a matrix, the phosphorescent label having an emission lifetime of about 1 microsecond or more. The porous membrane defines a detection zone within which is immobilized a capture reagent. The lateral flow assay device is contacted with the test sample. The detection zone is subject to one or more pulses of illumination to generate a detection zone. Thereafter, the intensity of the detection signal is measured. The amount of the analyte within the test sample is proportional to the intensity of the detection signal.

In the Office Action, previous independent claims 1 and 28 were rejected under *35 U.S.C. §103(a)* as being obvious over WO 97/09620 to Rylatt, et al. in view of U.S. Patent No. 6,770,220 to Klimant, et al. Rylatt, et al. is directed to a method for detecting an analyte. More specifically, the method employs a "test zone" on a support medium. The "test zone" contains a receptor that is capable of binding to the analyte, particularly when complexed to an analyte detection agent. A "calibration zone" is also disposed on

the support medium that contains a receptor capable of binding to a calibration agent. As correctly noted by the Examiner, however, Rylatt, et al. fails to disclose one or more limitations of the present claims. For example, Rylatt, et al. does not disclose the use of phosphorescent particles that comprise a phosphorescent label encapsulated within a matrix.

Nevertheless, Klimant, et al. was cited in combination with Rylatt, et al. in an attempt to render obvious previous independent claims 1 and 28. More specifically, the Office Action cited Klimant, et al. for the teaching of a phosphorescent label encapsulated within a solid particle. The asserted motivation for making this combination was that Klimant, et al. teaches the "benefit of luminescence measurements for biological and chemical analysis due to its high sensitivity and versatility . . . and to eliminate or greatly reduce phosphorescence signal quenching by interfering oxygen that is common during luminescence measurement."

Despite the general teachings of Klimant, et al. relating to phosphorescent particles, Applicants respectfully submits that no motivation whatsoever would have existed to incorporate such particles into a "lateral flow, membrane-based assay device" in the specific manner required by independent claim 64. The present claims are directed to a lateral flow assay device that employs a porous membrane (e.g., nitrocellulose). However, porous membranes present such a wide variety of problems for phosphorescent detection that no objective motivation or reasonable expectation of success would have existed to make the combination proposed in the Office Action. In lateral flow membrane-based assays, for example, the analyte is diluted by a liquid (e.g., test sample, diluent, etc.) flowing through the porous membrane, which reduces

its concentration. At such low analyte concentrations, the corresponding phosphorescent intensity is likewise low, thereby heightening the problem of background interference. Adding to this problem, the porous membrane also tends to reflect the excited illumination to such an extent that the intensity of the reflected illumination is even larger than the excitation illumination. Many membranes, such as nitrocellulose membranes, also exhibit strong fluorescence when excited in the UV and visible regions. This fluorescence may further interfere with the accuracy of phosphorescence measurements. In light of the above, Applicant respectfully submits that one of ordinary skill in the art would not have found it obvious to make the combination proposed in the Office Action.

Even if the references are somehow combined, however, the resulting combination would still fail to disclose one or more limitations of independent claim 64. For example, independent claim 64 requires that the phosphorescent label have an emission lifetime about 1 microsecond or more. This is desired so that the label still emits a significant signal well after any short-lived background signals dissipate. In the Office Action, the Examiner conceded the combination of Klimant, et al. and Rylatt, et al. fails to disclose this limitation, but nevertheless attempted to combine these references with the O'Riordan, et al. publication in an attempt to render obvious previous dependent claim 18 (which recited the claimed emission lifetime).

O'Riordan, et al. generally describes phosphorescent porphyrin labels for use in solid-phase immunoassays of AFP. Applicant notes, however, that no motivation would have existed to combine the teachings of O'Riordan, et al. and Klimant, et al. as suggested in the Office Action. Klimant, et al., as indicated above, is directed to the

incorporation of phosphorescent substances into a solid matrix to shield them from interfering substances (e.g., O_2). In stark contrast, the phosphorescent labels of O'Riordan, et al. are not at all encapsulated, but instead simply mixed with Na_2SO_3 to eliminate interference by molecular oxygen and other quenchers. (p. 5846). Due to the substantial differences in the fundamental construction and operation of the phosphorescent systems, one of ordinary skill in art would simply not have selectively picked and chosen certain aspects of O'Riordan, et al. for incorporation into Klimant, et al.

Applicant emphasizes that the issue in conducting an analysis under *35 U.S.C. § 103(a)* is not whether a theoretical re-design of a device is *possible* or that it might be *obvious to try* the modification. Instead, the issue hinges on whether the claimed invention as a whole would have been obvious. In this case, the Office Action parsed and dissected only certain portions of Klimant, et al. and O'Riordan, et al., and then used these dissected portions in a way that would require a substantial reconstruction of Rylatt, et al. Clearly, the Office Action is using the present application as a "blueprint" for selectively re-designing the references, which is improper under *35 U.S.C. § 103.* Thus, for at least the reasons set forth above, Applicant respectfully submits that one of ordinary skill in the art would not have found it obvious to modify the references in the manner suggested in the Office Action.

It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Diramio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Amendment.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully requested,

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